OUTLINE OF SECTION 8.1 – 8.3 ON DRUG LABELING

As proposed in the Draft Guidance

FORMATTING
Subsection numbers and titles in the Full Prescribing Information (FPI) must be bolded (e.g., **8.1 Pregnancy**) (§ 201.57(d)(7)). In addition, unique to the PLLR is the requirement for the inclusion of specific subheadings and headings under subheadings within subsections (e.g., Risk Summary). Subheading titles within these subsections should be italicized and/or underlined, and heading titles should be either italicized or underlined, and the approach used should be consistent throughout the labeling. Additional subdivisions of information are not recommended.

8.1 Pregnancy

Pregnancy Exposure Registry (omit if not applicable)

If there is a scientifically acceptable pregnancy exposure registry for the drug, the following statement must appear:

> "There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to (name of drug) during pregnancy."

The statement must be followed by contact information needed to enroll in or to obtain information about the registry.

Risk Summary (required subheading)

Provides 'risk statements' that describe for the drug the risk of adverse developmental outcomes based on all relevant human, data, animal data and the drug's pharmacology.

When applicable, risk statements must include a cross-reference to additional details in the relevant portion of the Data subheading in the **Pregnancy** subsection.

Clinical Considerations (omit if none of the headings are applicable)

Provides information to further inform prescribing and risk-benefit counseling.
Relevant information is presented under the following 5 subheadings:

Disease-associated maternal and/or embryo/fetal risk (omit if not applicable)

Dose adjustments during pregnancy and the postpartum period (omit if not applicable)

Maternal adverse reactions (omit if not applicable)

Fetal/Neonatal adverse reactions (omit if not applicable)

Labor or delivery (omit if not applicable)

Data (omit if none of the headings are applicable)

Describes the data that provide the scientific basis for the information presented in the Risk Summary and Clinical Considerations

Human Data (omit if not applicable)

Animal Data (omit if not applicable)

8.2 Lactation

Replaces the Nursing Mothers subsection

Risk Summary (required subheading)

Summarizes information on the presence of a drug and/or its active metabolite(s) in human milk, the effects of a drug and/or its active metabolite(s) on the breastfed child, and the effects of a drug and/or its active metabolite(s) on milk production

Clinical Considerations (omit if not applicable)

Provides information to further inform prescribing and risk-benefit counseling.

Minimizing exposure
Monitoring for adverse reactions

Data (omit if not applicable)

Describes the data that provide the scientific basis for the information presented in the Risk Summary and Clinical Considerations

8.3 Females and Males of Reproductive Potential (omit if none of the subheadings are applicable)

Includes information for these populations when

- There are recommendations or requirements for pregnancy testing and/or contraception before, during, or after drug therapy; and/or
- There are human and/or animal data suggesting drug-associated effects on fertility

Pregnancy Testing (omit if not applicable)

Contraception (omit if not applicable)

Infertility (omit if not applicable)